IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
Franklin *et al.*	)	Art Unit: 1615
	)	
Application No.: 10/586,597	)	Examiner: Neil S. Levy
	)	
Filing Date: April 4, 2008	)	Confirmation No.: 1640
	)	
For: NEMATACIDAL COMPOSITIONS AND METHODS OF USING THEM	)	

DECLARATION OF DR. GARY OSTROFF UNDER 37 C.F.R. § 1.132

MAIL STOP RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BALLARD SPAHR LLP
Customer Number 23859

Sir:

I, Gary Ostroff, hereby declare that:

1. I am an inventor of the subject matter described and claimed in the above-identified patent application.

2. I am a Professor of Molecular Medicine at the University of Massachusetts Medical School (UMMS) located in Worcester, Massachusetts.

3. I hold a Bachelors of Science (B.S.) degree from Delaware Valley College of Science and Agriculture and a Doctor of Philosophy (Ph.D.) degree from the University of Delaware. As the inventor of the yeast particle and glucan particle delivery technology, I am the world's expert in utilizing these particles for payload delivery. I first began working with glucan particles (GP) in 1988 as the Chief Scientific Officer at Alpha-Beta Technology, Inc., where I was the co-inventor of three (3) U.S. patents describing the use of GPs as phagocytic cell-targeted delivery vehicles. Working as a consultant and scientific advisor to Eden Research plc, the assignee of the above-identified patent application, I have

adapted the use of these particles for terpene delivery, which is described and claimed in this patent application. A copy of my curriculum vitae is attached.

4. I have read the Office Action mailed on April 18, 2011 by the United States Patent and Trademark Office. Specifically, I have read the Office Action's rejection of Claims 1, 17, 20-34, and 39-55 for an alleged lack of enablement.

5. Experiments conducted under my supervision have demonstrated that thymol is a key component of nematicidal compositions. Without thymol, the nematicidal compositions do not meet industry benchmarks for commercial efficacy.

6. Experiments conducted under my supervision have also demonstrated that compositions comprising hollow glucan particles encapsulating either geraniol or citral alone were not more effective than the current industry standard known as oxamyl, which is marketed as Vydate®. These experiments led us to conclude that the key active terpene in the mixture is thymol. In fact, nematicidal compositions comprising hollow glucan particles that encapsulate thymol and one or more other terpenes are more effective at killing nematodes than Vydate®.

7. For example, as shown in the attached Appendix, we tested a range of different nematicidal terpene compositions against various nematode species. Nematicidal compositions labeled B2Y comprise hollow glucan particles encapsulating thymol and geraniol, and nematicidal compositions labeled H2Y comprise hollow glucan particles encapsulating thymol and citral. These experiments demonstrated that compositions comprising hollow glucan particles encapsulating thymol and either geraniol or citral were, in most cases, more effective than Vydate®. While we tested these nematicidal compositions at various concentrations including 100 ppm, 250 ppm, and 500 ppm, the Appendix only presents data for the experiments conducted at 500 ppm.

8. Figure 1 of the attached Appendix shows the control of the migratory nematode *Trichodorus spp.* using various B2Y and H2Y nematicidal compositions. Figure 1 shows that all

variations of the B2Y and H2Y nematicidal compositions were more effective at killing this type of nematode than was the industry standard Vydate®.

9. Figure 2 of the attached Appendix shows the control of the migratory nematode *Tylenchorhynchus spp.* using various B2Y and H2Y nematicidal compositions. Figure 2 shows that all the variations of the B2Y and H2Y nematicidal compositions were more effective at killing this type of nematode than was the industry standard Vydate®.

10. Figure 3 of the attached Appendix shows the control of the migratory nematode *Pratylenchus penetrans* using various B2Y and H2Y compositions. Four of the six variations of the B2Y and H2Y nematicidal compositions were more effective at killing this type of nematode than was the industry standard Vydate®.

11. Figure 4 of the attached Appendix shows that the mean weight of the carrots increased following treatment with various B2Y and H2Y nematicidal compositions. Treatment with any of the variations of the B2Y and H2Y nematicidal compositions resulted in greater mean weight than did treatment with the industry standard Vydate®. The increase in the mean weight of the carrots indicates that the carrot crop is healthier due to the killing of the nematodes. Figure 4 represents the combined effect of the three aforementioned nematode species.

12. Figure 5 of the attached Appendix shows that the percentage yield of carrots increased following treatment with various B2Y or H2Y nematicidal compositions. Treatment with any of the variations of the B2Y and H2Y nematicidal compositions resulted in greater yield than did treatment with the industry standard Vydate®.

13. In short, the attached Appendix shows (i) that we could predictably make various nematicidal compositions comprising hollow glucan particles encapsulating thymol and one or more other terpenes, (ii) that we could routinely test the efficacy of these nematicidal compositions against the industry standard by measuring at least the survival rate of nematodes and the yield of the crop, and (iii) that we could determine through routine

experimentation the efficacy of these nematicidal compositions for killing multiple types of nematodes as compared to the industry standard.

14. I declare that all statements made herein of my own knowledge and belief are true and that all statements made on information and belief are believed to be true, and further, that the statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Gary Ostroff, Ph.D.
Professor of Molecular Medicine, UMMS

10/7/11

Date

Norma J. Mahoney

NORMA J. MAHONEY
NOTARY PUBLIC
COMMONWEALTH OF MASSACHUSETTS
MY COMMISSION EXPIRES 06/20/14

Gary R. Ostroff, Ph.D.

301 Bridle Path
Worcester MA 01604
Home: 508-752-9141
Email: gostroff@yahoo.com

SUMMARY: Over thirty years of research and pharmaceutical product development experience in the biopharmaceutical industry. Noted accomplishments in the development of carbohydrate and protein therapeutics, diagnostics, target discovery, assay development and small molecule drug screening from Discovery through Phase III clinical studies. Recent accomplishments include the development of the GlucaDel™ oral drug, protein, nucleic acid, small molecule and nanoparticle delivery technologies.

WORK EXPERIENCE:

1/08 – present University of Massachusetts Medical School
Research Professor
Program in Molecular Medicine
373 Plantation St
Worcester, MA 01605

8/05 - 1/08 University of Massachusetts Medical School
Research Professor
Department of Pediatrics
222 Maple Ave.
Shrewsbury, MA 01545

Academic research position focused on the human and diagnostic applications of the Glucan particle drug delivery technology. CoPI, co-investigator or collaborator on 17 NIH, State, Foundation and industrial grants utilizing the Glucan drug delivery technology to deliver DNA/siRNA/miRNA/antisense oligonucleotides, protein/peptides, small molecules, and nanoparticles for a wide range of therapeutic applications. Extensive collaborative interactions with the biopharmaceutical industry to develop commercial applications.

1/03 – 1/08 GlucaDel, Inc — Founder
301 Bridle Path — Chief Scientific Officer
Worcester, MA 01604

Founded GlucaDel to commercialize oral and systemic payload delivery properties of yeast beta glucan particles. Discovered and developed patent pending methods to load, trap and release a wide range of commercially relevant payloads (small molecule, peptides, oligonucleotides, proteins and expressing plasmid DNAs) into yeast glucan particles. Developed successful collaborative programs with academic and industrial partners to demonstrate proof of concept for the GlucaDel technology in *in vitro* and animal models of disease. International glycotechnology consultant.

5/01- 12/03	Biothera Pharmaceuticals	Vice President Research & Development
	3388 Mike Collins Dr.	Chief Technical Officer
	Eagan, MN 55121	Consultant

Led a world-wide academic-government-industry collaborative preclinical development effort evaluating oral yeast WGP™ glucan as a broad acting anti-infective immunomodulator, demonstrating effectiveness against endemic antibiotic-resistant infections, Class A bioterrorism infections and emerging infections in the developing world. Led the clinical development plans for selected infectious/cancer/radiation disease indications, with an oral yeast WGP™ glucan Phase I safety/biomarker clinical study completed in 2002, and cancer adjuvant immunotherapy trials planned for 2003.

Developed the radiation-protective yeast beta 1,3 glucan research program demonstrating preclinical proof of principle oral protective effects that has led to a novel government-industry development and marketing agreement with the Armed Forces Radiobiology Research Institute. Ongoing research initiatives are advancing to the clinical phase to test the protective effects of oral WGP Glucan treatment in cancer patients undergoing radiation and chemotherapy.

Led an academic-industry preclinical collaborative program successfully demonstrating the potential for oral and injectable yeast beta 1,3 glucans as cancer immunoadjuvants to traditional radiation and chemotherapies, and emerging monoclonal antibody and vaccine immunotherapies. Current efforts are focused on the licensing of this platform technology.

Led the technical support for the sales and marketing of oral yeast beta 1,3-glucans. These efforts resulted in building a >$1MM dollar bulk ingredient business in year 1, the launch of over 10 new dietary supplement products containing yeast WGP Glucan by our partners in US, European and Asian markets, and the national launch of a retail dietary supplement brand, Imucell™ WGP, in drug and mass merchant markets.

10/99-Present	Amerifit Nutrition, Inc.	Vice President Research & Development
	& Medical Foods, Inc.	Chief Scientist
	166 Highland Park Drive	Scientific Advisor
	Bloomfield, CT	Consultant

Directed the transition of Medical Foods from a boutique product development company to a functional food ingredient company with the responsibility for the development of four core technologies: (1) Fibercel® yeast beta glucan (for delivery of cardiovascular, immune, intestinal health benefits), (2) Fibercel® functional ingredient delivery system (encapsulation and delivery of a wide-range of food, vitamin, herbal and drug ingredients), (3) MaxAbsorb™ lipids (well tolerated and palatable source of rapidly absorbed structured omega-3 fatty acids for cardiovascular and neurological health benefits) and (4) Timed Release™ Glucose (for diabetics, controlled energy release, and appetite control benefits).

Led the technical aspects of the merger between Medical Foods and Amerifit Nutrition to develop a science-based dietary supplement company and to provide a value-added dietary supplement outlet for the Medical Foods' technologies. Championed the concept of combining the long-term nutritional benefits of dietary supplements with the immediate benefits of natural equivalents of over-the-counter drugs. Three new products

were launched embodying this concept: (1) Estroven® for peri- and menopausal woman delivering relief from hot flashes and sleeplessness, (2) Flex Able™ PM for joint support and sleeplessness, and (3) Flex Able™ Curcumin & MSM for joint support and pain relief. The impact of this concept combined with a consumer advertising campaign propelled Estroven to become the leading dietary herbal supplement in woman's health consumer unit sales for the past 8 years.

Managed the technical aspects of preclinical toxicology evaluations and large scale clinical studies testing the safety and efficacy of Estroven® formulations to relieve the symptoms of menopause as an alternative therapy to Hormone Replacement Therapy.

6/99-2004	Worcester Polytechnic University, Worcester, MA	Adjunct Professor Department of Biotechnology and Biology Bioengineering Institute
2/99-9/99	Ostroff Consulting	Principal

Consulted for 16 domestic and international companies to provide assistance in drug discovery, carbohydrate and protein pharmaceutical product development, diagnostic product development, and the functional food ingredient and dietary supplement industries.

1988- 1/99	Alpha-Beta Technology One Innovation Drive Worcester MA	Director Research & Development Vice President Research & Development Vice President Discovery Research

Chief Scientist from company inception built and managed a 70+ person R&D group.

Discovered and led the preclinical development of Betafectin^{R} PGG-Glucan, a carbohydrate anti-infective phagocytic leukocyte immunomodulator. The clinical development of Betafectin was recently suspended because of equivocal efficacy results in a confirmatory Phase III study for the prevention of serious post-surgical infections.

Oversaw the extramural preclinical evaluation of a range of PGG-Glucans for treating of antibiotic-resistant infections, accelerating acute and chronic wound healing, and reducing myelosuppressive-induced hematopoeitic leukopenia and function.

Discovered and led the development of Adjuvax™, a vaccine adjuvant marketed by Pierce Chemical Company and Fujisawa to the research and veterinary community.

Led the development of Fibercel^{R}, a novel dietary fiber licensed to Medical Foods Inc.

Codiscovered and led the development of Cholazol™, a functionalized carbohydrate-based bile acid sequestrant hypercholesterolemic agent.

Instituted and led a small molecule antifungal drug discovery program based on novel cell-wall polysaccharide and enzyme targets. Directed the acquisition of MycoTox, Inc. to provide whole cell assay screening capabilities to complement the novel drug-development targets.

Discovered three novel cell-wall targets/HTS assays and led screening efforts to identify a collection of six potent, broadly active, cell wall targeted drug leads with *in vivo* candicidal activity.

1984 – 1988.	Genzyme Corporation Kendall Square, Cambridge MA	Senior Research Microbiologist Microbiology Group Leader

Initiated microbiology, molecular genetics, rDNA and fermentation R&D activities as the second research scientist in the company. Managed a 20 person multi-national R&D group.

Led the R&D of a microbial process for the production of hyaluronic acid currently being marketed as multiple products to prevent surgical adhesions with current sales over $100 MM. Material currently in development for tissue repair and osteoarthritis treatments.

Initiated, developed and led a recombinant DNA and fermentation-based microbial and yeast strain improvement plan to develop a diagnostic enzyme program resulting in a 10-fold decrease in manufacturing costs and current sales of over $50 MM.

Codirected the R&D to produce the ionophore, valinomycin, in a critical 3-month time frame allowing the company to show a profit and go public the following year.

Directed the R&D to clone and overproduce glycoprotein-modifying enzymes to support the glycoprotein enzyme product line, and glycoprotein remodeling technology (Ceredase^{R} and Cerezyme^{R} glucocerbrosidase).

Developed and led the early phases of the cloning and high-level expression program for Cerezyme^{R} recombinant glucocerbrosidase currently being marketed for the treatment of Gaucher's disease with current sales over $750 MM.

1983-1984	University of Massachusetts Medical School 55 Lake Avenue North, Worcester MA	Postdoctoral Fellow

Developed a funded research program in the laboratory of Dr. Neal Brown to clone the herpes simplex and human DNA replication enzyme DNA polymerase . Funded by American Cancer Society.

1977-1982	University of Delaware Newark DE	Graduate Research Fellow

Developed a patented bifunctional cloning system for Gram positive bacteria. Funded by Cetus Corp.

EDUCATION

Ph.D.	1982	University of Delaware Newark DE School of Life and Health Sciences
B.S.	1976	Delaware Valley College of Science and Agriculture Doylestown PA Department of Biology and Chemistry

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GRANTS Available on request

PUBLICATIONS

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3. HUANG H, **OSTROFF GR**, LEE CK, WANG JP, SPECHT CA, LEVITZ SM, 2010. Robust stimulation of humoral and cellular immune responses following vaccination with antigen-loaded β-glucan particles. mBio.00164-10. Published online July 20, 2010.

4. HUANG H, **OSTROFF** GR, LEE CK, WANG JP, SPECHT CA, LEVITZ SM, 2009. DISTINCT PATTERNS OF DENDRITIC CELL CYTOKINE RELEASE STIMULATED BY FUNGAL B-GLUCANS AND TOLL-LIKE RECEPTOR AGONISTS. INFECT IMMUN. 77(5):1774-81.

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PATENTS

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2. *Patchen, M.L.; Jamas, S; Easson, DD; Ostroff; G.R.; Very high molecular weight beta-glucans. United States Patent Application. 20060247205.*

3. GINNS, E.I; OSTROFF, G.R; Novel Therapy for Lysosomal Enzyme Deficiencies. 2004 *United States Patent Application 20060083718.*

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16. Jamas, S; Easson, D.D., Jr; **Ostroff, G.R.** Method for producing aqueous soluble beta (1,3) glucans. *US Patent 5,663,324*

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20. Jamas, S; Easson, D.D., Jr; **Ostroff, G.R.** Use of aqueous soluble glucan preparations to stimulate platelet production. *US Patent 5,532,223.*

21. Jamas, S; Easson, D.D., Jr; **Ostroff, G.R.** Methods for immune system activation with modified .beta.-glucan. *US Patent 5,504,079 World Patent 9103248.*

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25. **OSTROFF G.R**; PENE J J. Molecular cloning with bifunctional plasmid vectors in Bacillus-subtilis mutants and substantially stably transformed mutants of Bacillus-subtilis and method for utilizing the transformed mutants. *US Patent 4595660.*

Abandoned Patents

1. **Ostroff G.R**; Stevenson, T.T; Yalpani M; Liang J. A derivatized polysaccaride bile acid sequestrant for reducing cholesterol. ABY93-01A

2. **Ostroff G.R.** Use of Bis (Diazo) compounds as antifungal agents. ABY98-01.

3. **Ostroff G.R.** Beta (1,3) glucan microfibril assembly assay. ABY98-02.

4. **Ostroff G.R.** Beta (1,6) glucan synthesis and cell wall assembly assay. ABY98-03.

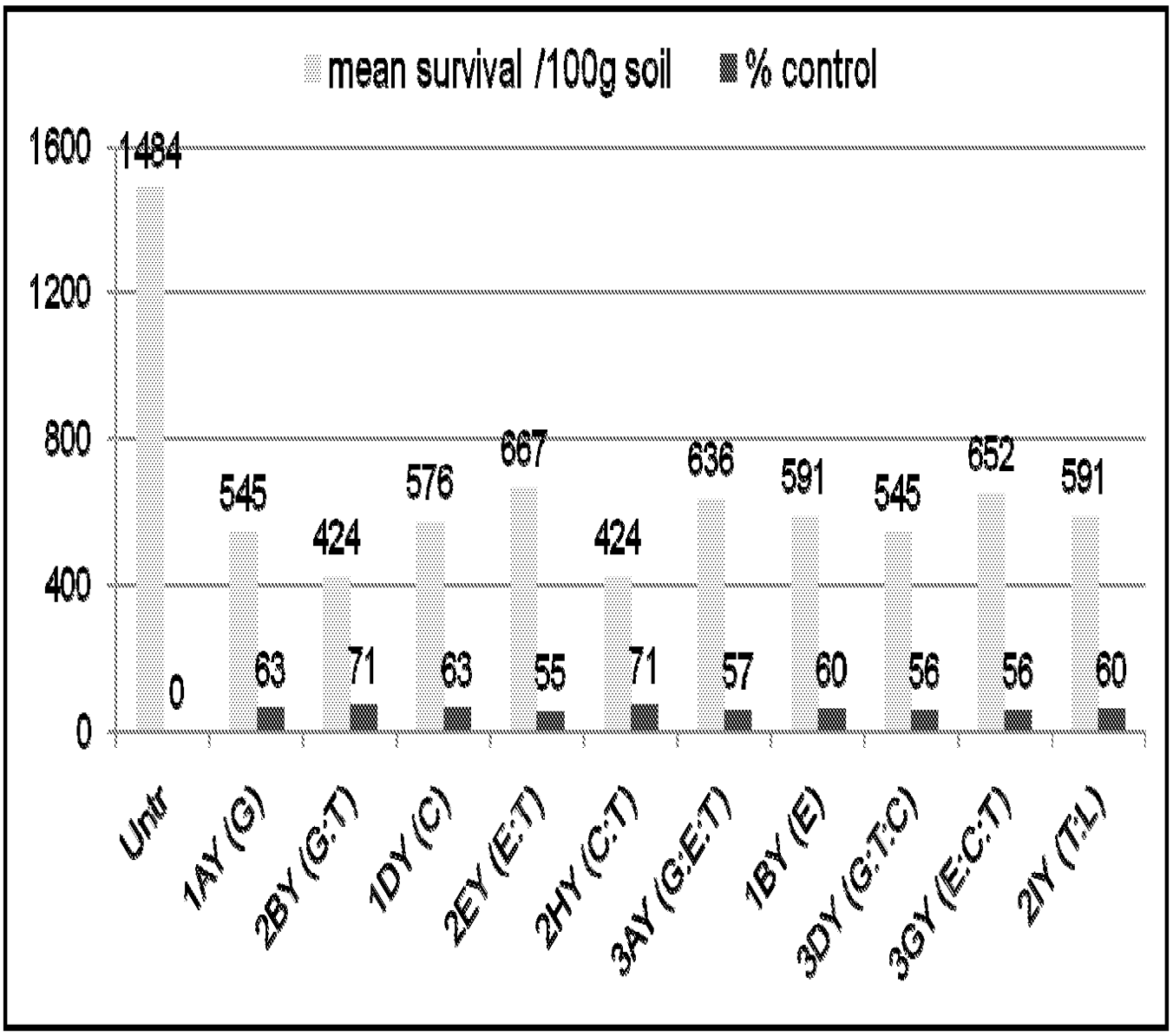
5. **Ostroff G.R.** Assays for agents which alter cell wall biopolymer synthesis. ABY98-04.

6. **Ostroff G.R.** Chitin Microfibril assembly assay. ABY98-05.

7. Selitrennikoff C.P; **Ostroff G.R.** Ketol isomerase inhibitors. ABY98-06.

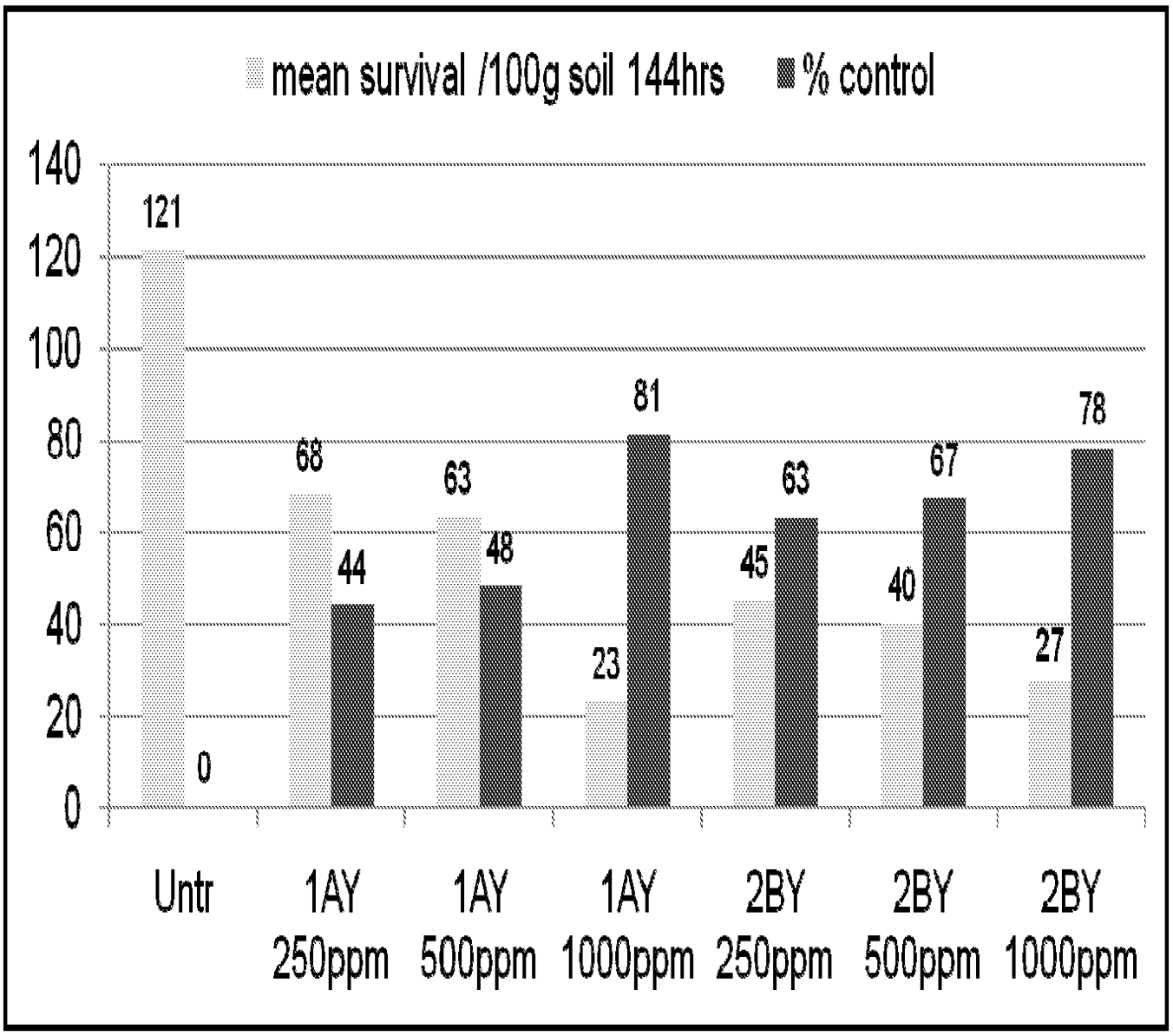
Appendix - Figure 1A

Control of *Meloidogyne incognita* Nematodes in Greenhouse Soil



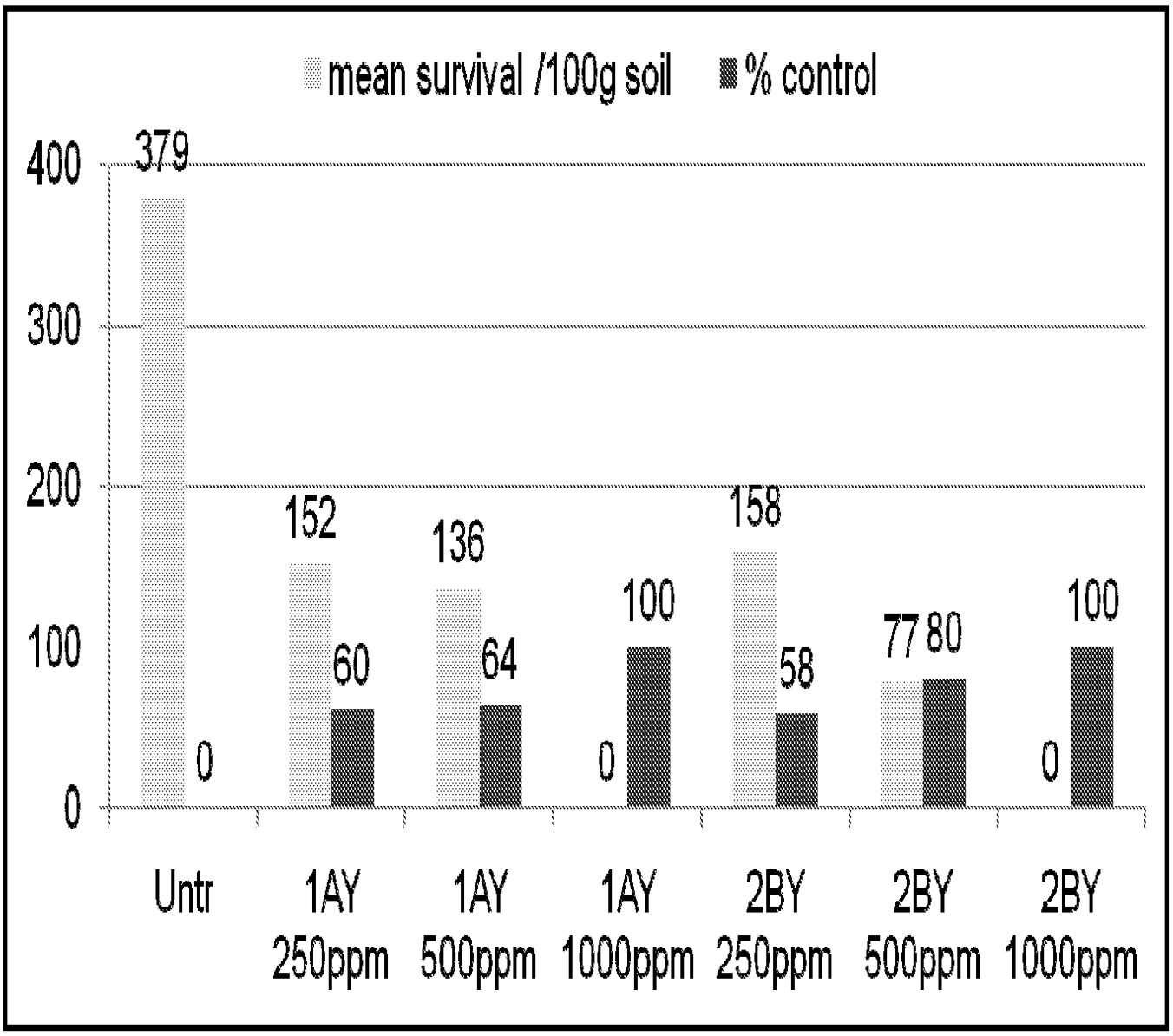
Appendix - Figure 1B

Control of *Meloidogyne incognita* Nematodes in Greenhouse Soil



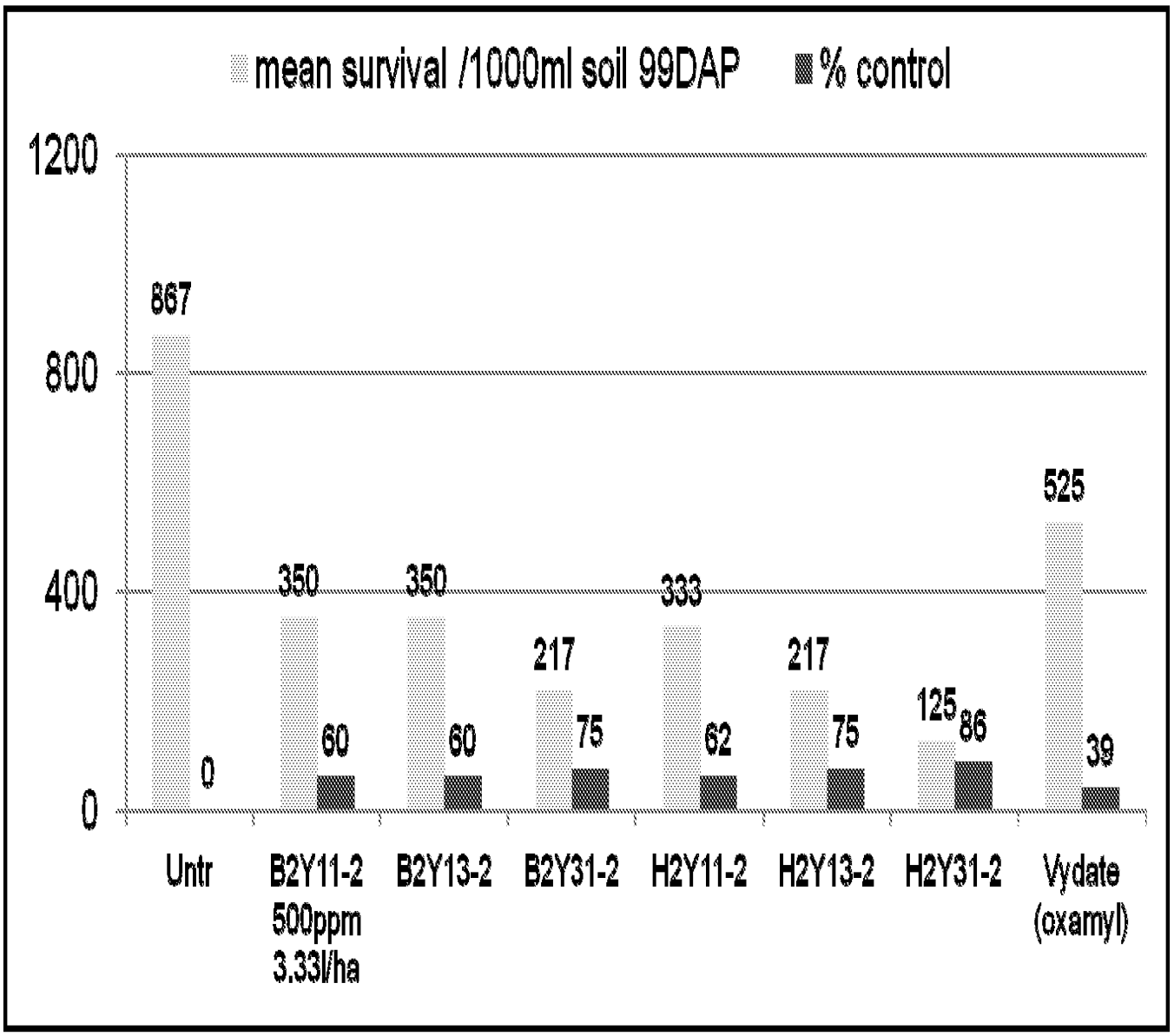
Appendix - Figure 1C

Control of *Meloidogyne incognita* Nematodes in Tomatos



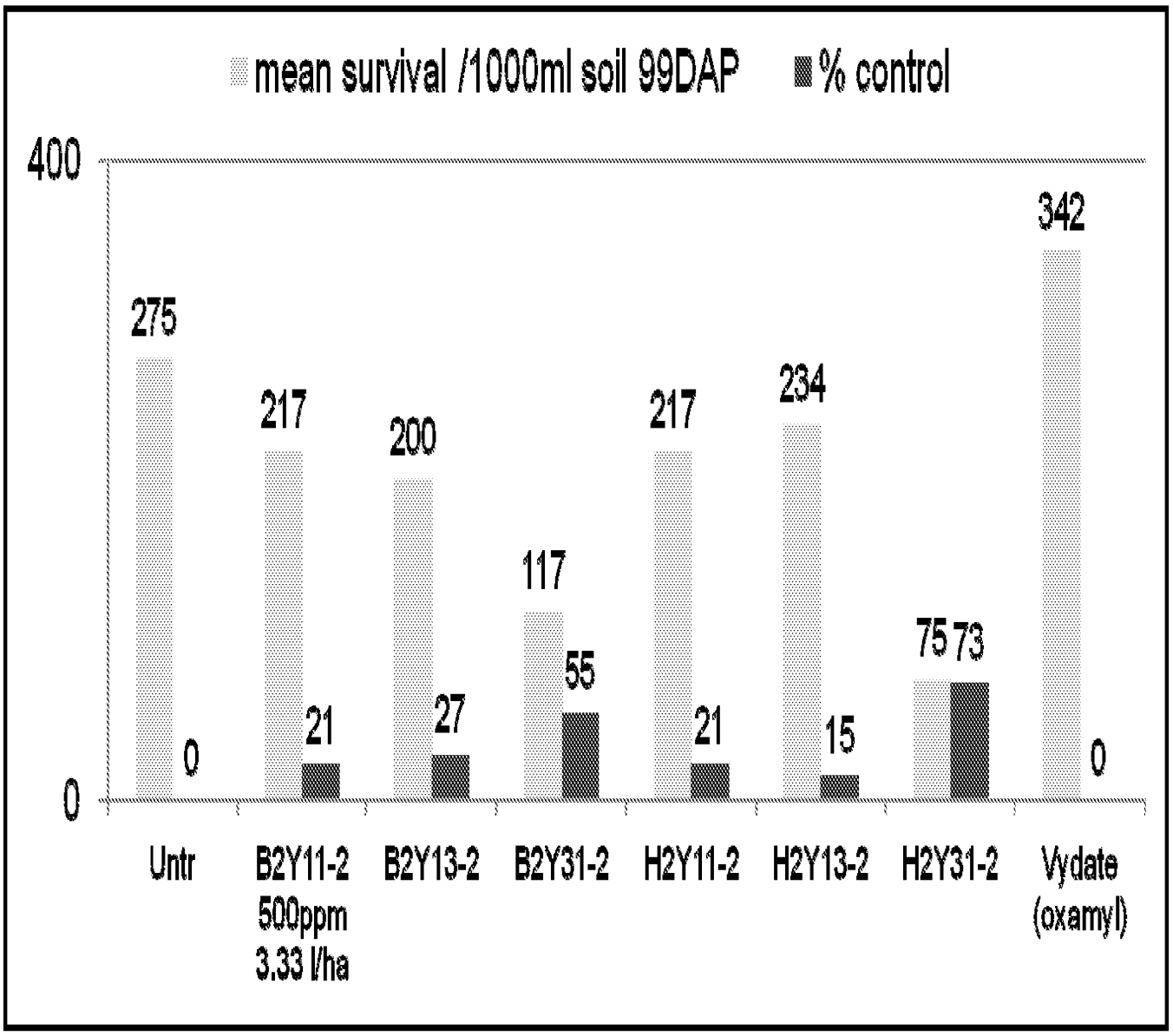
Appendix - Figure 2

Control of migratory nematodes *Trichodorus spp.* in Carrots



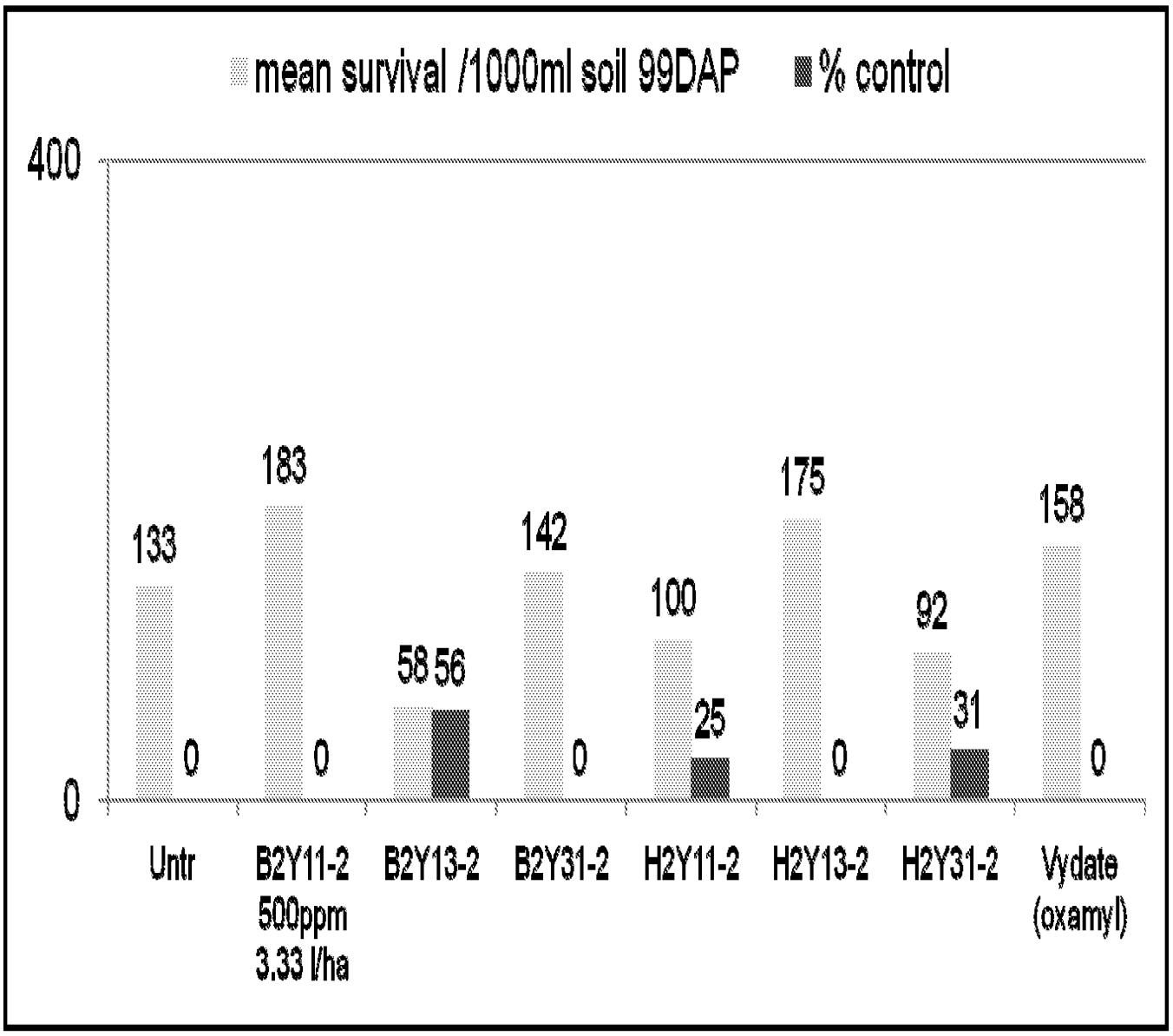
Appendix - Figure 3

Control of migratory *Tylenchorhynchus spp.* nematodes in Carrots



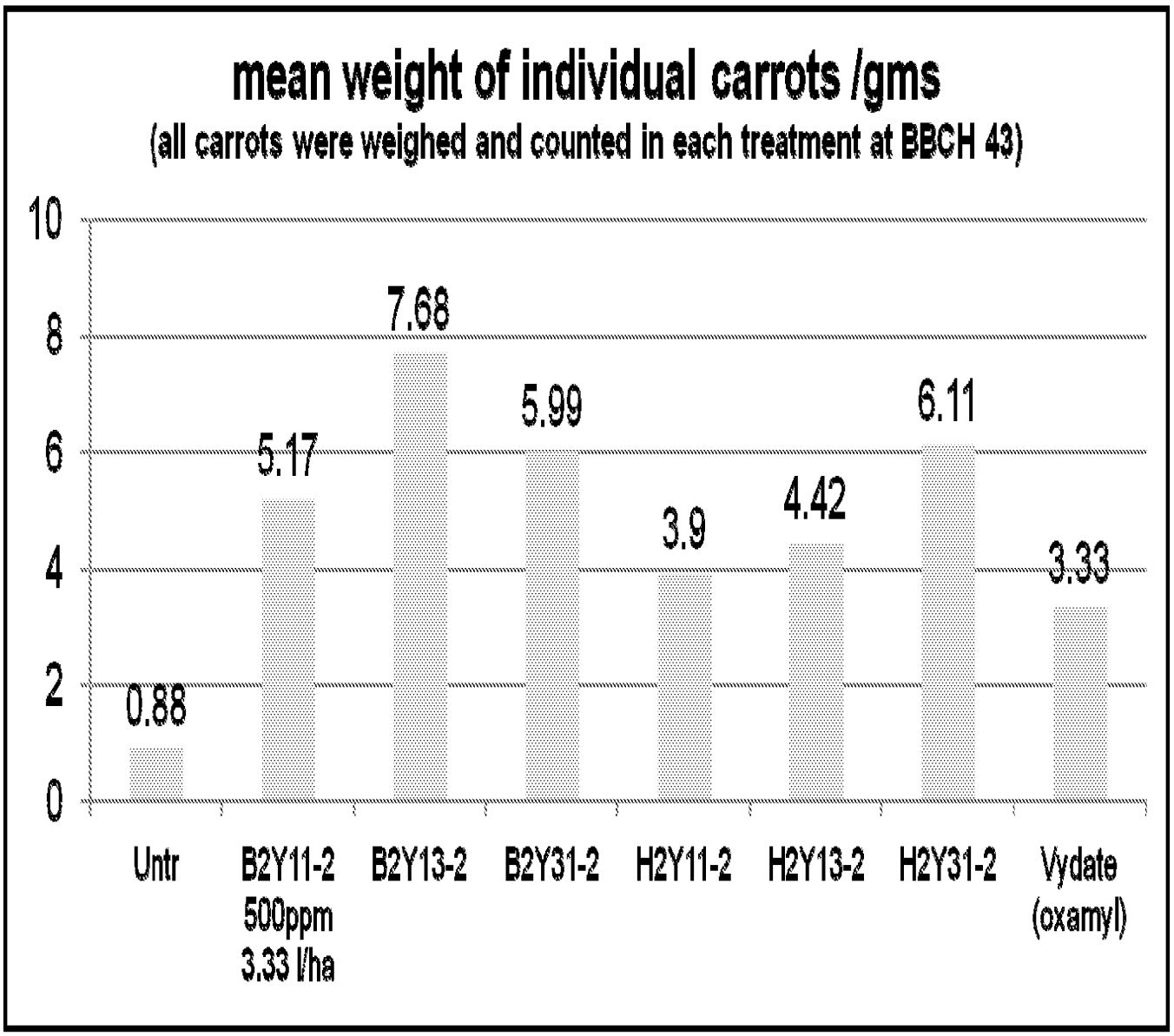
Appendix - Figure 4

Control of migratory *Pratylenchus penetrans* nematodes in Carrots



Appendix - Figure 5

Control of Various Nematodes in Carrots as Evidenced by Yield



Appendix - Figure 6

Control of Various Nematodes in Carrots as Evidenced by Yield